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| 10/722,945 | 11/26/2003 | John J. Price | 016434-095400 (ETH-5089) | 9633 |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/722,945 PRICE, JOHN J. Office Action Summary Art Unit Examiner Melanie Tyson -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 27 April 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-8 and 10-31 is/are pending in the application. 4a) Of the above claim(s) 13 and 15-21 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 1-8,10-12,14, and 22-31 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

information Disclosure Statement(s) (PTO/S5/06)
Paper No(s)/Mail Date ______.

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 April 2009 has been entered. Claims 9 and 32-34 are canceled. Claims 13 and 15-21 are withdrawn from consideration.

Response to Arguments

Applicant's arguments with respect to claims 1-8, 10-12, 14, and 22-31 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skil in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.

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> Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 10-12, 14, 22-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dery (U.S. Patent No 3,394,704 - cited 6/27/07) and Morton (U.S. Patent No. 1,558,037 - cited 10/29/08). It is noted that sufficient structure has been recited for increasing the bond between the adhesive and the hole (for example, see claim 22). Therefore, 112, sixth paragraph, has not been invoked.

Dery discloses an armed suture (see entire document) comprising a needle (5) having first and second opposed ends and a blind hole (9) formed in the first end and extending longitudinally, the hole including an upper edge, a sidewall, a bottom wall having a conical tip, and a length therebetween (see Figure 3) having a first diameter greater than the diameter of a multi-braided or monofilament (for example, see column 3, lines 16-18) suture (6), wherein the hole may accommodate sutures larger and smaller than the suture shown, thus may accommodate a range of differently-sized sutures therein. Dery discloses the adhesive permits the suture to be inserted into the hole and forms an annular mass that substantially surrounds the end of the suture along the length of the hole (for example, see 64-70 and column 3, lines 25-31). Dery fails to disclose the blind hole has a second diameter proximate the bottom wall having a conical tip that is greater than the first diameter proximate the upper edge and a means located inside the hole for increasing the bond between the adhesive and the hole.

Morton discloses an armed suture (see entire document) comprising a blind hole (2). Morton teaches the blind hole has a second diameter proximate the bottom wall that

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is greater than the first diameter proximate the upper edge, thus forming a bottle shape. Morton teaches that such a configuration helps to effect a secure anchoring of the suture therein (for example, see page 2, lines 43-45). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Morton to the blind hole of Dery would have yielded predicable results and resulted in an improved system, namely, a system that provides a blind hole that enables a larger amount of adhesive to be contained proximate the bottom wall having a conical tip, thus enhancing the security of the suture therein. With further respect to claim 31, a bottle-shaped blind hole would yield a bottle-shaped interlock between the suture and the hole.

Morton further discloses an embodiment in which the inside of the hole is scarified (or roughened bond increasing means; see claims 1 and 22) in such a matter as to provide adequate anchorage of the suture therein (for example, see page 2, lines 60-63). Thus, it would have been recognized by one of ordinary skill in the art that applying the known technique taught by Morton to the blind hole of Dery would have yielded predicable results and resulted in an improved system, namely, a system that provides greater anchorage between the hole and adhesive, in turn enhancing anchorage between the suture and the hole, thus further reducing the risk of the suture detaching from the needle during use. With further respect to claim 26, the Dery's blind hole includes a bottom wall having a conical tip, thus the roughened blind hole would yield a roughened conical tip.

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Claims 11 and 23-25 are being treated as product by process limitations, in that "said suture hole is formed by laser drilling," "said roughened portion is reamed," "said roughened portion is laser drilled," and "said roughened portion is etched," refers to the process of forming the suture hole and its surface and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art. the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, an armed suture as described above wherein the suture hole is formed by laser drilling, and the roughened surface is reamed, laser drilled, or etched, is directed to the method of making the armed suture hole and its roughened surface and not to the final product made. It appears that the product disclosed by Derv as modified by Morton would be the same or similar as that claimed: especially since both applicant's product and the prior art product have the same final structure of an armed suture comprising a blind hole having a roughened surface.

Regarding claim 12, Dery does not disclose the hole is polished after drilling, thus the hole is considered to be unpolished.

Claims 2-8 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dery and Morton** as applied to claim 1 above, and further in view of

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Korthoff et al. (U.S. Patent No. 5,156,615 - cited 10/29/08). Dery as modified by Morton discloses the claimed invention except for an adhesive that is curable as claimed or that the adhesive is specifically cyanoacrylate.

Korthoff discloses bonding a suture attached to a needle using adhesives (see entire document). With respect to claims 2-8, Korthoff teaches that cyanoacrylate (which is curable by exposure to electromagnetic radiation, such as UV light, and further curable by a second curative agent, such as water or heat) is a preferred adhesive for bonding the suture within a hole in the needle, since cyanoacrylate possesses excellent adhesive characteristics (for example, see column 9, lines 18-23). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use cyanoacrylate as the adhesive, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. Utilizing cyanoacrylate would ensure an excellent bond, thus further reducing the risk of the suture detaching from the needle during use.

With further respect to claims 27-29, the applicant admits that a low viscosity, UV-curable, cyanoacrylate adhesive having a cyanoacrylate secondary cure mechanism is well known and is available under the name LOCTITE Product 4302. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use LOCTITE Product 4302 as the adhesive, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./ Examiner, Art Unit 3773 May 28, 2009 Application/Control Number: 10/722,945 Art Unit: 3773 Page 8

/(Jackie) Tan-Uyen T. Ho/ Supervisory Patent Examiner, Art Unit 3773